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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,257	12/21/2001	Peter Krulevitch	IL-10580	6642

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EXAMINER

BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/032,257

Applicant(s)

KRULEVITCH ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 16-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 16-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-5 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krulevitch et al.(US 5,985,217 or US 6,319,474) in view of Pourahmadi et al.(WO 99/33559).

The reference of Krulevitch et al. discloses a microfabricated biopsy and analysis instrument (30) that includes a body (See Figure 3C) including a silicon substrate (31) and a

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glass substrate (32) positioned together. The device includes a cutter with a sharp edge (35) and a tapered opening (34). A specimen chamber is defined by the volume between the tapered opening (34) and microchannel (40). This chamber is located in the silicon substrate and glass substrate immediately below the cutter (See Figure 3C). The device includes a specimen treatment and analysis chamber (40) located in the silicon substrate and glass substrate abutting and connected directly to the specimen chamber and located adjacent the specimen chamber. The device includes an analysis unit (47) in the specimen treatment and analysis chamber (40).

While the reference of Krulevitch et al. discloses that the specimen treatment and analysis chamber (40) is communicated with chamber (46) and discloses that the specimen within chamber (40) can be treated with a chemical (See column 5, lines 20-47), the instant claims differ by reciting that the body of the device includes a PCR chamber with a heating unit directly connected to the specimen treatment and analysis chamber.

The reference of Pourahmadi et al. discloses that it is known in the art to combine microfabricated sample preparation device, including tissue slicing or cutting with microfabricated analyte detection and/or microfabricated polynucleotide amplification. The reference of Pourahmadi et al. discloses a microfabricated biopsy and genetic analysis instrument that includes a cutter section and specimen chamber (103) located below the cutter section. See page 20, line 27, to page 21, line 10, which discloses that the opening of the specimen chamber (sample port, 103) can include a mesh that slices a tissue specimen. The instrument includes a specimen treatment section (including treatment chambers 107, 119, 122, 141) located adjacent the specimen chamber (103) and a PCR reaction chamber section that is integral or abuts the specimen treatment section. See page 12, lines 13-26, which discloses that the PCR reaction

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chamber (143) can be integral or separable relative to the sample treatment section of the instrument.

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the device of the reference of Krulevitch et al. with a PCR chamber directly connected to the sample treatment chamber for the known and expected result of further processing the tissue sample within the same device as suggested by the reference of Pourahmadi et al. while providing the advantages associated with the structure of the device of Krulevitch. Note the reference of Krulevitch et al. discloses that the disclosed device can be incorporated into a system microfluidic system using existing microvalves and pumps (See column 5, lines 49-59) and that the device is intended to be used for acquiring specimens for DNA analysis (See column 1, lines 62-65).

With respect to the use of the consisting language, provision of a device that is devoid of reagents and/or controllers, would have been obvious when providing a disposable device wherein the control devices can be reused with other devices. Also, based merely on the source of the sample to be detected and/or the reagents employed, whether or not the system includes a dna purification zone would have been well within the purview of one having ordinary skill in the art. Furthermore, the presence of purification sections and other sample processing zones can fall within the claimed "specimen treatment and analysis chamber".

With respect to claim 2, the reference of Krulevitch et al. discloses that the cutting edge (35) has a smooth edge with atomic sharpness capable of cutting very thin specimens of tissue.

With respect to claim 3, the reference of Krulevitch et al. discloses that the cutter is constructed of silicon.

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With respect to claims 4 and 5, the reference of Pourahmadi et al. discloses the use of microchannels (See Figure 2) to connect the sample chamber (103) with the PCR reaction chamber (143). Also the reference discloses the use of planar members, including glass, to form the device (See page 26, line 35, to page 27, line 28). The reference of Krulevitch et al. discloses construction of the microchannel device of silicon and glass substrates (See column 3, lines 1-12 of Krulevitch et al.).

With respect to claim 16, the specimen treatment and analysis chamber (40) includes a chemical solution channel (40), an optical window (32) and optical detection system (47).

With respect to claim 17, the structures of the modified primary reference as suggested above would all be formed in the same body.

With respect to claim 18, the reference of Krulevitch et al. discloses that the cutting edge (35) has a smooth edge with atomic sharpness capable of cutting very thin specimens of tissue.

With respect to claim 19, the reference of Krulevitch et al. discloses the location of the optical analysis window and detection device with respect to specimen and analysis chamber (40) which is in communication with the specimen chamber.

Terminal Disclaimer

5. The terminal disclaimers filed on 12/20/05 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patents 5,985,217 and 6,319,474 have been reviewed and are accepted. The terminal disclaimers have been recorded.

Response to Arguments

6. With respect to the rejections of claims 1-5 and 16-19 under 35 USC 112, second paragraph, the rejections have been withdrawn in view of the amendments to the claims and associated comments (See page 6 of the response filed 12/20/05).

7. With respect to the rejection of claims 1-5 and 16-19 under 35 USC 103 over the combination of the references of Pourahmadi et al. and Krulevitch et al., Applicants argue (See pages 6-13 of the response filed 12/20/05) that the rejection is improper for the following reasons:

a) The limitations of amended claims 1-5 and 16-19 are not found in the reference of Pourahmadi et al. Applicants stress that the reference of Pourahmadi et al. is a highly complex system and would not support a 35 USC 102 rejection of the instant claims.

b) The reference of Krulevitch et al. also fails to show the elements and combination of elements of amended claims 1-5 and 16-19.

c) Since neither of the references of Pourahmadi et al. or Krulevitch et al. show all of the elements or combination of elements, the references cannot be combined to meet the instant claim language.

d) There is not combination of the references of Pourahmadi et al. and Krulevitch et al. that would produce the combination of elements as recited in amended claims 1-5 and 16-19. Applicants stress that there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings.

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In response to arguments a) and b) above, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to arguments c) and d) above, the Examiner maintains that the combination of the references as recited in the 35 USC 103 rejection of record meets the structure of the claimed device for the reasons specifically set forth in the rejection of record. Note the reference of Krulevitch et al. discloses a majority of the structural elements absence a PCR chamber and heater. The reference of Pourahmadi et al. discloses that it is known in the art to combine a tissue-cutting device with a PCR device. Furthermore, the reference of Krulevitch et al. discloses that the tissue samples obtained by the device can be used for DNA analysis (See column 1, lines 62-65) and that the device can be incorporated into a microfluidic system (See column 5, lines 49-59). The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Examiner is of the opinion that since the reference of Krulevitch et al. discloses a cutting device which can be used for DNA analysis and can be incorporated into a microfluidic and the reference of Pourahmadi et al. discloses that a tissue cutting or sampling device can be combined with a PCR device, one of ordinary skill in the art would have readily recognized the advantages of using the cutting device disclosed by the

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reference of Krulevitch et al. to provide a sample to a PCR analysis device. Furthermore, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



William H. Beisner
Primary Examiner
Art Unit 1744

WHB